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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,842	12/20/2001	Alain Moussy	065691-0265	1460

22428 7590 05/21/2004

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,842	MOUSSY ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-36* is/are pending in the application.

4a) Of the above claim(s) *2 and 15-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 and 15-36 are pending.

1. Applicant's election with traverse of group I, claims 1 and 3-13 in Response to Restriction Requirement filed 03/31/04 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the inventions must be both independent and distinct and an undue search burden on the examiner. However, MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required.

Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria, indicates that inventions recognized divergent subject matter and that a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. All the above establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in the previous Office Action and above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2 and 15-36 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1 and 3-13 are under consideration in the instant application.

2. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claim 12 recites " ... the mast cells that are IL-3 dependent cells". There is insufficient antecedent basis for this limitation in the claims, since base Claim 1 does not recite "mast cells that are IL-3 dependent cells".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 0212448 or by WO 01/85096.

WO'448 teaches a method of identifying and screening of compound capable for modulating survival, proliferation and function of mast cells that will not effect CD34+ expressing cells, comprising contacting purified mast cells with a test compound and assessing the ability of the test compound to modulate cell survival and/or proliferation (see entire document, Abstract and pages, 4, 9 and 13 in particular). It is noted that the term "modulating mast cell survival" is interpreted in been able to decrease mast cell survival or to promote mast cell death thus a compound that would be capable of decreasing cell survival would inherently be capable of depleting mast cells. WO'448 teaches a method of culturing mast cells in vitro in suitable culture medium comprising IL-3 (see page 2 and example 4 in particular). WO'448 teaches a method of identifying and screening of compound capable for modulating survival and proliferation of mast cells, wherein cell survival and proliferation is measured by ^{3}H- thymidine incorporation or BrdU incorporation (see example 8 and 9 in particular).

WO'096 teaches a method for identifying compound capable of selectively targeting and eliminating mast cells without effecting other hematopoietic cells (see entire document, Abstract and pages 2 and 7 in particular). WO'448 teaches a method of culturing mast cells in vitro in suitable culture medium comprising IL-3 (see pages 1, 13 and 16 in particular). WO'448 teaches a method of identifying compound capable of selectively targeting and eliminating mast cells by monitoring mast cells viability i.e. proliferation or the induction of cell death or apoptosis in mast cells using various apoptosis assays, including trypan blue exclusion method (see page 9 and 15 in particular). WO'096 teaches that said compounds may be inhibitors of kinases (see page 19 in particular).

The reference teaching anticipates the claimed invention.

7 . The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3-5, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0212448 or over WO 01/85096 each in view of ATCC Catalog NOs: TIB-64;CRL-2034, CRL-2036, CRL-2037,TIB-152,CCL-213,CRL-1593.2;CCL-240, CRL-2258, CRL-2392.

The teaching of WO 0212448 or WO 01/85096 has been discussed, supra.

The claimed invention differs from the reference teaching in that the WO 0212448 or WO 01/85096 does not teach: a specific mast cells, as recited in claim 3; or specific other hematopoietic cells as recited in claim 4; a specific concentration of compounds as recited in claims 5 and 6; a specific concentration of IL-3 in a culture media as recited in claim 12 and specific method of detecting cell death as recited in claims 9-11.

ATCC Catalog NOs: TIB-64;CRL-2034, CRL-2036, CRL-2037,TIB-152,CCL-213,CRL-1593.2;CCL-240, CRL-2258, CRL-2392 teach that mast cells lines as recited in claim 3 and hematopoietic cells as recited in claim 4 are well known and commercially available.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of ATCC Catalog NOs: TIB-64;CRL-2034, CRL-2036, CRL-2037,TIB-152,CCL-213,CRL-1593.2;CCL-240, CRL-2258, CRL-2392 to those of WO 0212448 or WO 01/85096 to obtain a claimed method for identifying compound capable of depleting mast cells, wherein mast cells lines as recited in claim 3 and hematopoietic cells as recited in claim 4.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because it is clear that both the prior art and applicant used similar approaches to specifically target and deplete only mast cells without effecting other hematopoietic cells. It would be immediately obvious to one of ordinary skill in the art at the time the invention was made to test if the compounds identified by the methods taught by WO 0212448 or WO 01/85096 that can specifically target and deplete mast cells without effecting other hematopoietic cells would also be able to deplete a specific strain of mast cells, as recited in claim 3 that are well known and commercially available, as taught by ATCC Catalog NOs: TIB-64;CRL-2034, CRL-2036, CRL-2037, with out effecting a specific other hematopoietic cells, as recited in claim 4, that are well known and commercially available, as taught by ATCC Catalog NOs: TIB-152,CCL-213,CRL-1593.2;CCL-240, CRL-2258, CRL-2392. When the prior art method is the same as a method described in the specification, it can be assumed the method will obviously perform the claimed process absent a showing of unobvious property of the recited cell stains. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 5 , 6 and 9-12 are included because it would be conventional and within the skill of the art to : (i) identify the a specific concentration of compounds as recited in claims 5 and 6; or (ii) to identify the a specific concentration of IL-3 to be used in a culture media, as recited in claim 12 ; or (iii) to used a specific method to determine the extent of cell death or apoptosis, as recited in claims 9-11. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Com. v. Electro Materials Corp. of America 202 USPQ 22 (DC SINY); and In re Burckel 201 USPQ 67 (CCPA).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0212448 or over WO 01/85096 as applied to claims 3-5, 9-12 above, and each further in view of US Patent 6,339,100.

The teaching of WO 0212448 or WO 01/85096 has been discussed, supra.

The claimed invention differs from the reference teaching in that the WO 0212448 or WO 01/85096 does not teach a method of identifying compound capable of depleting mast cells, wherein compound is inhibitors of tyrosine kinases, such as recited in claim 13.

US '100 teaches a method to specifically target c-kit expressing mast cells by identifying specific tyrosine kinase inhibitors, such as MAPK that can specifically kill and thus deplete mast cells (see entire document, Abstract and column 3 and 4 in particular). US '100 teaches that it is important to identify and block tyrosine kinases involved in downstream transducing the signal from c-kit receptor (see column 10 in particular). US '100 teaches that identifying a tyrosine kinase inhibitors that can specifically kill mast cells is a novel therapy aimed directly at a cause of diseases mediated by mast cell (see column 1 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US '100 to those of WO 0212448 or WO 01/85096 to obtain a claimed method of identifying compound capable of depleting mast cells, wherein compound is selected from inhibitors of tyrosine kinases, as recited in claim 13.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because identifying a tyrosine kinase inhibitors that can specifically kill mast cells is a novel therapy aimed directly at a cause of diseases mediated by mast cell as taught by US '100 and can be done by the method taught by WO 0212448 or WO 01/85096. Although the references are silent about specific inhibitors of tyrosine kinases recited in claim 13, it would be conventional and within the skill of the art to identify and select a specific inhibitors of

tyrosine kinases, recited in claim 13. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claim is allowed.

14. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
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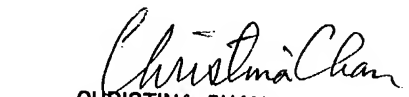
May 17, 2004



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